

REMARKS

Responsive to the communication mailed on March 23, 2004, claims 47-71 have been renumbered 72-96 and this amendment replaces the amendment filed on December 22, 2003.

This application has been amended in a manner that is believed to place it in condition for allowance at the time of the next Official Action.

By way of the present amendment, claims 47-71 have been cancelled. New claims 72-96 have been added. Support for new claims 72-96 may be found in the original claims and generally throughout the specification. The Examiner's attention is also respectfully directed to the present specification at page 25, lines 1-16; page 35, lines 10-13; page 31, line 3 to page 32, line 1; and Examples 45-91.

Claims 22-35 were rejected under 35 USC §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. It is believed that this rejection has been obviated by the present amendment. In particular, the Examiner's attention is directed to claims 85-96, wherein the claims have been amended to recite a step of storing and/or transporting an aqueous preparation of thrombomodulin.

In imposing the rejection, the outstanding Official Action alleged that the recitation, a "method for maintaining an aqueous injection preparation of thrombomodulin" was indefinite.

As noted above, claims 22-35 have been cancelled and new claims 85-96 have been added. In the interest of advancing prosecution, new claims 85-96 recite a --method for storing/transporting an aqueous injection preparation of thrombomodulin in a non-frozen or a non-freeze dried liquid form--. As a result, it is believed that claims 85-96 have been drafted in a manner so as to obviate the contention that the claimed invention was indefinite.

Claims 22-29 and 35-46 were rejected under 35 USC §102(b) as allegedly being anticipated by KUNIHIRO et al. 5,202,421. It is believed that the present amendment obviates this rejection.

Applicants respectfully submit that KUNIHIRO et al. fail to disclose or suggest the claimed aqueous injection preparation or claimed method for storing/transporting an aqueous injection preparation of thrombomodulin in a non-frozen or non-freeze dried liquid form.

Applicants believe that KUNIHIRO et al. fail to teach an aqueous injection preparation that is packed aseptically in a container, or a composition that is capable of being stored and/or transported as set forth in the claimed invention. Moreover, applicants believe that KUNIHIRO et al. fail to disclose or suggest an aqueous injection preparation containing the components as set forth in the claimed invention.

KUNIHIRO et al. teach a composition that is administered to animals for test purposes. The composition is

prepared and then quickly administered to an animal. KUNIHIRO et al. do not disclose or suggest maintaining or preserving thrombomodulin or the necessity of maintaining thrombomodulin under aseptic composition.

This stands in contrast to the claimed invention. As noted above, the claimed invention is directed to an aqueous injection preparation of thrombomodulin for being stored/transported in a non-frozen or non-freeze dried liquid form. The injectable solution in the syringe is capable of being stored or transported in the form of an aqueous solution. The quality of the soluble thrombomodulin is maintained and the solution is kept under aseptic conditions.

Indeed, the Examiner's attention is respectfully directed to claim 72, lines 9-11, wherein the claim recites that the preparation has been packed aseptically in a container and is kept aseptically in said container while being stored/transported. Claim 73 recites that the container filled with aqueous solution is a prefilled syringe preparation and the aqueous solution is in a syringe vessel sealed aseptically by a cap and a stopper. KUNIHIRO et al. fail to disclose or suggest any of these recitations.

The Examiner's attention is also respectfully directed to new claims 74 and 75. New claims 74 and 75 recite that the container and the prefilled syringe preparation are further packaged by other package materials such as a sheet or a carton.

Applicants believe that KUNIHIRO et al. teach away from such recitations. The recitations are completely unnecessary in the preparation disclosed by KUNIHIRO et al.

Claims 76 and 89 are directed to specific amino acid sequences. Applicants note that KUNIHIRO et al. fail to disclose these sequences.

Indeed, KUNIHIRO et al. also do not disclose or suggest the components of the claimed aqueous injection preparation. While KUNIHIRO et al. state that Lubrol is added to the solution in case of the "human placental thrombomodulin" for the purpose of solubilization, applicants submit that there is no teaching that the surfactant is added to soluble thrombomodulin. Indeed, human placental thrombomodulin is not soluble but rather insoluble.

Thus, in view of the above, it is believed that KUNIHIRO et al. never disclose or suggest the claimed invention.

Claims 22-29, 31-33, and 35-46 were rejected under 35 USC §103(a) as allegedly being unpatentable over KUNIHIRO et al. in view of CHARNOW et al. It is believed that the present amendment obviates this rejection.

In imposing the rejection, the Official Action acknowledges that KUNIHIRO et al. do not specifically teach a syringe containing the disclosed thrombomodulin preparation. In an effort to remedy this deficiency, the outstanding Official Action cites to the publication by CHARNOW et al. The Official

Action contends that the publication teaches the risks and deleterious effects of injecting air into the human body.

However, the publication is directed to nursing procedures and is not concerned with storing or preserving thrombomodulin. CHARNOW et al. fail to suggest an aqueous injection preparation of thrombomodulin for being stored/transported in a non-frozen or non-freeze dried liquid form. As a result, it is believed that the proposed combination of KUNIHIRO et al. in view of CHARNOW et al. fails to render obvious the claimed invention.

In view of the present amendment and the foregoing remarks, therefore, it is believed that this application is now in condition for allowance, with claims 72-96, as presented. Allowance and passage to issue on that basis are accordingly respectfully requested.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

YOUNG & THOMPSON

  
Philip Dubois, Reg. No. 50,696  
745 South 23<sup>rd</sup> Street  
Arlington, VA 22202  
Telephone (703) 521-2297  
Telefax (703) 685-0573  
(703) 979-4709

PD/lk